

Remarks

Claims 34, 36-37, 40-41, 43-44 and 47 are currently pending.

Regarding the withdrawn rejection under 35 U.S.C. 112, second paragraph, the Examiner has indicated that the previous rejection has been withdrawn in view of the Applicants' arguments.

Applicants have amended Claim 34. Basis for the amendments can be found throughout the Specification, more particularly on the bottom of page 8, top of page 9 and bottom of page 10. Applicants submit that no new matter has been added.

REJECTIONS UNDER 35 U.S.C. § 112

I. The Rejected Claims Comply with the Written Description Requirement

Claims 34, 36-37, 40-41, 43-44, and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner alleges that the "skilled artisan cannot envision the detailed chemical structure of all the derivatives encompassed in the claims." (Paper No 20060929, page 3). The Applicants submit the present amendments address the Examiner's concerns. Claim 34 has been amended to recite that the GLP-1 molecule contain one modification as recited. Therefore, Applicants submit that a skilled artisan would be able to envision all the compounds encompassed by the claims. As such, Applicants respectfully request withdrawal of the rejection.

II. The Rejected Claims satisfy the Enablement Requirement

Claims 34, 36-37 and 40 are rejected under 35 U.S.C. 112, first paragraph as not reasonably providing enablement for any GLP-1 derivative or variant or amide form thereof. The Examiner alleges that the "specification is not enabling for any GLP-1 derivative or variant or amide form thereof."

Applicants submit the present claims are enabled. Applicants have amended the claims to indicate that the GLP-1 molecule have one modification as recited in the claims.

The Examiner has not provided a reasonable basis to doubt the enablement of the present claims. The Examiner has alleged that the claims are not enabled and has provided a

general discussion regarding the predictability of changes in a protein's structure to the stability. Applicants submit that this does not provide a reasonable basis to conclude that the specific changes in a GLP-1 molecule as recited in the present claims would not lead to a formulation with increased stability. Applicants have indicated in the specification the particular pH range, the particular buffers and particular tonicity modifiers to achieve a shelf stable formulation. (pages 6-7 of the Specification). Applicants submit that given the teaching provided by the Specification and the scope of the claimed invention, the present claims are enabled. Applicants respectfully request withdrawal of the rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 34, 36, 40-41, 43 and 47 are rejected under 35 U.S.C. 102 (e) as being anticipated by Hoffman (U.S. Patent No. 6,358,924, hereafter "Hoffman"), based on the recitation in Hoffman of a pH of "about 6.5 to about 9.0." Applicants submit that Hoffman does not disclose each and every feature of the Applicants' claims and as such, Hoffman does not anticipate.

Anticipation requires that each limitation of a claim be found, expressly or inherently, in a single reference. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1367, (Fed. Cir. 2005). Further, the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. In re Baird, 16 F.3d 380, 382 (Fed. Cir. 1994). The Examiner alleges that the recited claims are anticipated by Hoffman as "Hoffman also teach[es] a pH range of 6.5-9.0 which falls within the recited range." (Paper No. 20060929, page 10). Applicants would like to clarify that the pH range of 6.5-9.0 would not fall within the range of 8.2 to 8.8 as alleged by the Examiner.

In addition, Applicants submit that the disclosure of a pH range of 6.5-9.0 in Hoffman does not disclose the recited pH range of 8.2 to 8.8 with sufficient specificity to anticipate. Recently the Federal Circuit held that a smaller range out of a larger genus was not anticipated by the disclosure of the larger genus. Atofina v Great Lakes Chemical Corp., 441 F.3d 991, 999 (Fed. Cir. 2006). In Atofina, the claimed range was 330 to 450 degrees with the prior art disclosing a range of 100 to 500 degrees. The Federal Circuit held "no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim." *Id.*

The pH range of Hoffman, similarly, does not anticipate the Applicants' recited pH range. Hoffman discloses a pH range of 6.5 to 9.0. In the context of pH, this range is a large range and thus a large genus. This range encompasses values which range from slightly acidic to basic values including neutral values. Applicants are claiming a narrow, specific pH range of 8.2 to 8.8. Applicants' claimed range is similar to the range in Atofina which the court found was not anticipated by the larger range. The claimed range in Atofina encompassed 30% of the larger genus and was found not to anticipate "[g]iven the considerable difference between the claimed range and the range in the prior art " Id. Applicants' claimed range encompasses a genus encompassing 24% $((8.8-8.2)/(9.0-6.5) \text{ or } 0.6/2.5)$ of the prior art range. As the Applicants' range is smaller than the range in, Applicants submit Hoffman does not sufficiently specify the claimed range such that the claimed range is anticipated.

SUMMARY AND CONCLUSION

Applicants respectfully assert that the application is in condition for allowance. The claims are novel and clear in their meaning.

If, for any reason, the Examiner feels that a telephone conversation would be helpful in expediting the prosecution of this case, the Examiner is urged to call me.

Respectfully submitted,

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